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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/666,451	09/19/2003	Anthony D. Prescott	EAG-023	8367

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EXAMINER	
ISABELLA, DAVID J	
ART UNIT	**PAPER NUMBER**
3738	

DATE MAILED: 12/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/666,451	PRESCOTT ET AL.	
	Examiner	Art Unit	
	DAVID J. ISABELLA	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 September 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-12,15-18,27-29,31-41,43-45,47 and 50-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *14-18,29,31-39 and 41* is/are allowed.

6)☒ Claim(s) *1,3-12,27, 28,40,41,43-45,47,50-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Status of the Claims

Status of the Claims

Claims 1,3-12,14-18,27-29,31-41,43-45,47,50-54 are pending.

Claims 2,19-26,30,42,46,48-49 have been cancelled. Claims 52-54 have been newly added.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 50 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 50 depends from cancelled claim 48.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,4,5,6 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Shea, et al (429693).

Shea et al discloses a stapedial prosthesis sized to be implanted as a replacement for the stapes between the incus and the oval window of the middle ear, comprising: a body defining a bucket sized to at least partially receive a portion of the incus, and a shaft having a length sufficient to extend from the incus to the oval window; and b) a handle coupled to said bucket. Shea utilizes stainless steel as the material for the handle. Applicant's claim is directed to "spring-loaded handle coupled to the bucket". Looking to the specification to determine the metes and bounds of the term "spring loaded" examiner directs applicant's attention to page 24, lines 8+ through page 25, lines 1+.

"During the initial step of the insertion procedure, the bail handle 104 is rotated to the side of the bucket 106 having the upper opening 114 for the positioning tool (i.e., opposite the notch 140). The surgeon then gently moves the incus process (in the direction of arrow 202), rotates the prosthesis (in the direction of arrow 204), and sets the lenticular the bucket 106 into process 16."

Based on this sole disclosure, examiner maintains that the steps outlined in applicant's specification does not distinguish over the same steps as disclosed by Shea, et al. See columns 4 and 5.

During the insertion procedure, bail 18 is rotated to the side of bucket portion 12 having the opening the bore 30 (the position shown in dashed lines in FIG. 8). The surgeon then rotates bail 18 upwardly (in the direction indicated by the arrow in FIG. 8) so that bail 18 passes through a plane containing both bail 18 and the longitudinal axis of prosthesis 10 (a position which may be denominated "center") and moves further upwardly ("overcenter"). This movement requires bail 18 to pass over surfaces 34 of cams 32 and thus bail 18 must be sufficiently resilient to deform for this purpose. Upon reaching the end of tapered surfaces 34, bail 18 resumes

its original shape (best shown in FIG. 7) with its sides substantially parallel and closely adjacent bucket portion 12. The surgeon continues the upward rotation of bail 18, if necessary, until it is in proper position surrounding long process 20 of the incus. Any downward rotation of bail 18 now is prevented because of the stop means provided by shoulders 36 of cams 32. Thus, any tendency of bucket portion 12 to become dislodged from its engagement with lenticular process 14 of the incus will be curbed by the locking action of bail 18 and shoulders 36.

Examiner contends that the language of "requires bail to pass over surfaces 34 of cams 32 and thus bail must be sufficiently resilient to deform for this purpose. Upon reaching the end of tapered surfaces 34, bail 18 resumes its original shape" enables the handle of Shea to meet the limitations of "spring loaded" as claimed by applicant.

Claim 4, as worded does not appear to distinguish over the conformation of the bucket and U-shaped handle of Shea, et al. Certainly, the handle has two ends and once inserted into the bucket, the handle is subjected to load.

Claim 5, the holes of Shea et al are configured diametrically opposite on the bucket.

Claims 6 and 7, see notch 26 in the rim which terminates above the holes of the bucket of Shea et al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 27,28 and 52-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shea, et al (429693) as applied to claim 1 above, and further in view of Beyer (2792958) or Kulbacki (3593880).

Shea, et al discloses a stapedial prosthesis sized to be implanted as a replacement for the stapes between the incus and the oval window of the middle ear, comprising: a body defining a bucket sized to at least partially receive a portion of the incus, and a shaft having a length sufficient to extend from the incus to the oval window; and b) a handle coupled to said bucket. Shea et al teaches a preferred method for attaching the bail handle to the body. In column 4, lines 24+ Shea et al states that the coupling of the bail to the body may be employed by a variety of well known mounting techniques.

> sumes its original shape. Although bail 18 is shown in the drawings as being pivotally mounted to bucket portion 12 by the means just described, a variety of well-known mounting techniques may be utilized to provide the necessary pivotal movement of bail 18 with respect to bucket portion 12.

Each of Beyer and Kulbacki show different technique for mounting the bail to the body of the devices. To use either technique as shown by Beyer and Kulbacki to mount the bail to the body of the device of Shea, et al would have been obvious equivalents to one with ordinary skill in the art based upon design and engineering considerations.

Claims 1,3-7,48-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shea, et al (4292693) in view of Antonelli, et al (6726719) and further in view of Beyer (2792958) or Kulbacki (3593880) as applied supra.

Shea et al discloses a stapedial prosthesis sized to be implanted as a replacement for the stapes between the incus and the oval window of the middle ear, comprising: a body defining a bucket sized to at least partially receive a portion of the incus, and a shaft having a length sufficient to extend from the incus to the oval window; and b) a handle coupled to said bucket. While Shea et al, an older patent, utilizes stainless steel, the art teaches that titanium and stainless steel are well known for their spring-like properties and their use as a spring in the otic art is well documented, see Antonelli, et al.. To fabricate the wire handle of Shea et al out of titanium for its superior properties including spring-like performance to reduce the chances of deforming the handle after the handled has been subjected to external would have been an obvious substitution of equivalent elements as taught by Antonelli, et al. Each of Beyer and Kulbacki show different technique for mounting the bail to the body of the devices. To use

either technique as shown by Beyer and Kulbacki to mount the bail to the body of the device of Shea, et al would have been obvious equivalents to one with ordinary skill in the art based upon design and engineering considerations.

Claim 3, if not inherent, the use of biocompatible commercial grade 4 Ti would have been obvious to one with ordinary skill in the art as one of the many choices from the approved materials listed in the ASTM handbook.

Claim 4, as worded does not appear to distinguish over the conformation of the bucket and U-shaped handle of Shea, et al. Certainly, the handle has two ends and once inserted into the bucket, the handle is subjected to load.

Claim 5, the holes of Shea et al are configured diametrically opposite on the bucket.

Claims 6 and 7, see notch 26 in the rim which terminates above the holes of the bucket of Shea et al.

Claim 9, as broadly worded the handle of Shea, et al is rotatably coupled to the bucket.

Claims 10 and 12, see rejection to claim 4 supra.

Claim 11, see prosthesis of Antonelli, et al.

Claim 13, the structure of Shea et al as modified would inherently yield a spring loaded handle as broadly claimed.

Claim 27 see stapedial prosthesis of Shea et al.

Claim 28, the language of the claim does not preclude the intermediate product where the first and second ends are not coupled.

Claims 48 and 49, see rejection to claim 1 supra.

Claims 8,11,12,14,40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shea et al (4292693) in view of Antonelli, et al (6726719) as applied to claim 1 above, and further in view of Muller (6540661).

Muller teaches a bucket type capturing mechanism comprising slots formed therein. While the bucket of Muller is not intended for capturing the incus, the principle of providing slots in a wall member to increase wall flexibility is well known in any art. To provide slots in the bucket of Shea et al to increase the wall flexibility so as to offer the surgeon a more effective capturing of the incus would have been obvious to one with ordinary skill in the art from the teachings of Muller.

Claims 11 and 12, see body composition of the slotted bucket of Muller.

Claim 14, the slots in the bucket of Shea et al would offer the function of adjusting the diameter of the bucket by manipulation of the wall segments and the segments would retain the adjusted diameter if the applied force exceeds the modulus of the material.

Claims 15-17, while Muller is silent as to the dimension of the slot, it appears that in comparing the two devices, applicant's and Muller, the slot would approximately fall within the range as claimed.

Claim 18, the bottom of the bucket of Shea et al is closed.

Claim 40, the slots in the bucket of Shea et al would offer the function of adjusting the diameter of the bucket by manipulation of the wall segments and the segments would retain the adjusted diameter if the applied force exceeds the modulus of the material.

Allowable Subject Matter

Claims 14-18,29-39,41 are allowed.

Response to Arguments

Applicant's arguments filed 9/22/2005 have been fully considered but they are not persuasive. With respect to claim 52, the device is devoid of the spring loaded concept and examiner is treating the addition of the handle to the bucket as one with ordinary skill in any art. The features of attaching a handle to a bucket are well established and may be applied to the combination of Shea et al. With respect to claim 1, applicant is not allowed to read the specification into the claims. The limitations of the claims are considered in the broadest light and do not necessarily encompass the intended limitations as set forth in the specification. Stainless steel, as most metals, inherently possess spring like properties and would meet the limitations of the claim as broadly worded.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID J ISABELLA whose telephone number is 703-308-3060. The examiner can normally be reached on MONDAY-FRIDAY.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, CORRINE MCDERMOTT can be reached on 703-308-2111. The fax phone

number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DAVID J ISABELLA
Primary Examiner
Art Unit 3738

DJI
12/22/2005